510(k) Summary, K120781

AUG 9 2012

Manufacturer
Fuji Systems Corporation
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Contact
Yoshihiko Semba
General Manager, Director
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Date of Preparation
July 25, 2012

Product Names

Generic Name	*Classification*	*Product Code*	*Trade Name*	*Model No.*
Percutaneous Catheter	21 CFR 870.1250 Class II	DQY	CELLO Balloon Guide Catheter	1610560 (6 F)
				1610561 (6 F)
				1610570 (7 F)
				1610571 (7 F)
				1610580 (8 F)
				1610590 (9 F)

Predicate Device
Concentric Balloon Guide Catheter, K021899

Device Description

The CELLO Balloon Guide Catheter is a coaxial-lumen, braid-reinforced, variable stiffness catheter with two radiopaque markers on both the distal and proximal ends of the balloon and a bifurcated luer hub on the proximal end. A compliant silicone balloon is mounted on the distal end. Balloon Guide Catheter dimensions and recommended inflation volumes are indicated on the product label. Each catheter is supplied with an appropriately-size Dilator.

The CELLO Balloon Guide Catheters are used in hospitals or other health care facilities which are equipped with trained personnel and specialized equipment to perform peripheral and/or neurovascular procedures.

The CELLO Balloon Guide Catheter is used for facilitating the insertion and guidance of intravascular catheters into selected blood vessels in the peripheral and neurovasculature. The tip of the catheter features a balloon of silicone rubber. Radiopaque markers identify the proximal and distal ends of the balloon. The shaft is a dual lumen type with coaxial structure featuring a built-in braided stainless steel coil.

The materials of construction resemble those used in many other similar catheters. The shaft is made of polyurethane, polyamide, stainless steel and PFA; the balloon is silicone. Patient contact is of limited duration, less than 24 hrs.

Intended Use

The CELLO Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neurovasculature systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.

Comparison of Technological Characteristics, compared to the Predicate

Device	***Proposed***	***Predicate***	***Consideration***
Device Name	CELLO Balloon Guide Catheter	Concentric Balloon Guide Catheter	(N/A)
Device Description*	The CELLO Balloon Guide Catheter is a coaxial-lumen, braid-reinforced, variable stiffness catheter with two radiopaque markers on both the distal and proximal ends of the balloon and a bifurcated luer hub on the proximal end. A compliant silicone balloon is mounted on the distal end. Balloon Guide Catheter dimensions and the recommended balloon inflation volumes are indicated on product label. A dilator is provided with each catheter.	Concentric and Merci Balloon Guide catheters are coaxial lumen, braid-reinforced, variable stiffness catheters with a radiopaque marker on the distal end and a bifurcated luer hub on the proximal end. A compliant balloon is flush mounted on the distal end. Balloon Guide catheter dimensions and maximum recommended balloon inflation volume are indicated on product label. If indicated on product label, a dilator is provided.	Similar technological characteristics
Size	6F, 7F, 8F, 9F	8F, 9F	8F and 9F are the same
Effective length	920 mm to 1020 mm	800 to 950	Overlap from 920 to 950 mm
Material/Shaft	Polyurethane, Polyamide, Stainless steel, PFA	Polyurethane, Stainless steel	Similar materials
Material/Balloon	Silicone rubber	Silicone rubber	Same
Sterilization	Ethylene oxide	Ethylene oxide	Same

*Verbatim from each device's IFU.

Nonclinical Tests, CELLO Balloon Guide Catheters

Test	*Results*	*Conclusion*
Surface	Free from extraneous matter, process and surface defects.	Pass
Force at Break	All joints meet reliability/confidence requirements in statistical confidence limits test	Pass
Freedom from Leakage	Shall not leak liquid when inflated. Air shall not leak into the hub during aspiration.	Pass
Tip Configuration	Distal tip smooth, rounded, tapered or similarly finished.	Pass
Hubs	Comply with ISO 594-1 and ISO 594-2	Pass
Freedom from Leakage and Damage on Inflation	No leakage or evidence of damage, such as herniation or bursting of the shaft or balloon.	Pass
Dimensional Verification	All dimensions meet reliability/confidence requirements in statistical confidence limits test	Pass
Balloon Preparation, Deployment and Retraction	Catheters can be advanced to intended sites within a realistic tortuous path model where other devices can be deployed distally and retracted; all devices could be retracted without damage	Pass
Balloon Rated Burst Pressure (RBP)	All balloons meet reliability/confidence requirements in statistical confidence limits test	Pass
Balloon Fatigue	All balloons withstand 20 cycles of inflation	Pass
Balloon Compliance	All balloons have predictable change in size with pressure	FIO*
Balloon Inflation-Deflation Time	All balloons inflate and deflate predictably	FIO*
Flexibility and Kink	All catheters meet reliability/confidence requirements in statistical confidence limits test	Pass
Torque Strength	All models can be torqued at least 180° when the distal tip is fixed in a tortuous path model	FIO*
Radiopacity	Radiopaque markers are visible during angiography under a variety of conditions	FIO*

* For Information Only

Nonclinical Tests, Dilator

Test	*Results*	*Conclusion*
Surface	Free from extraneous matter, process and surface defects.	Pass
Force at Break	All joints meet reliability/confidence requirements in statistical confidence limits test	Pass
Freedom from Leakage	Shall not leak liquid when inflated. Air shall not leak into the hub during aspiration.	Pass
Tip Configuration	Distal tip smooth, rounded, tapered or similarly finished.	Pass
Hubs	Comply with ISO 594-1 and ISO 594-2	Pass
Freedom from Leakage and Damage on Inflation	No leakage or evidence of damage, such as herniation or bursting of the shaft or balloon.	Pass

Biocompatibility, CELLO Balloon Guide Catheters

Test	*Results*	*Conclusion*
L29 MEM Elution Test-ISO	Non-Cytotoxic	Pass
Kligman Maximization Test	No Sensitization	Pass
Intracutaneous Injection Test	Non-irritant	Pass
Systemic Injection Test-ISO	No acute toxicity	Pass
Rabbit Pyrogen Test (Material Mediated)-ISO	Non-pyrogenic	Pass
Hemolysis- Direct Contact	Non-hemolytic	Pass
Hemolysis-Rabbit Blood—ASTM Indirect Contact	Non-hemolytic	Pass
Complement Activation—Direct Contact	Non-Complement Activation	Pass
Complement Activation Assay—ISO Indirect Contact	Non-Complement Activation	Pass
In-vivo Thrombogenicity	Patent vessels No thrombus	Better thrombo-resistance than control

Biocompatibility, Dilator

Test	*Results*	*Conclusion*
L29 MEM Elution Test-ISO	Non-Cytotoxic	Pass
Kligman Maximization Test	No Sensitization	Pass
Intracutaneous Injection Test	Non-Irritant	Pass
Systemic Injection Test-ISO	No acute toxicity	Pass
Rabbit Pyrogen Test (Material Mediated)-ISO	Non-pyrogenic	Pass
Hemolysis- Direct Contact	Non-hemolytic	Pass
Hemolysis-Rabbit Blood—ASTM Indirect Contact	Non-hemolytic	Pass
Complement Activation—Direct Contact	Non-Complement Activation	Pass
Complement Activation Assay—ISO Indirect Contact	Non-Complement Activation	Pass
In-vivo Thrombogenicity	Less thrombus than control	Better thrombo-resistance than control

Clinical Tests

No clinical testing was submitted to support this premarket notification.

Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the CELLO Balloon Guide Catheter is substantially equivalent to the legally marketed predicate device.

The design of the CELLO Balloon Guide catheter resembles that of the predicate with regard to its principle of operation: each catheter shaft includes an internal stainless steel braid surrounded by polymer. The balloon is made from silicone rubber and its position can be identified during angiography because of radiopaque markers.

The intended use of the CELLO Balloon Guide Catheter is substantially equivalent to that of the predicate.

The patient population of the CELLO Balloon Guide Catheter is substantially equivalent to that of the predicate.

The CELLO Balloon Guide Catheter is substantially equivalent to the predicate device with respect to the anatomical sites where the device is used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 9 2012

Fuji Systems Corporation
c/o Paul Mason, PhD
Consultant
3250 Second Avenue
San Diego, CA 92103

Re: K120781
CELLO Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 26, 2012
Received: July, 27, 2012

Dear Dr. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number (if known): K120781

Device Name: CELLO Balloon Guide Catheter

Indications for Use:

The CELLO Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vasculature systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120781